K061297

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	The Anspach Effort 4500 Riverside Drive Palm Beach Gardens, FL 33410
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Date Prepared	January 11, 2007
Device Name	Anspach iMRI Surgical Drill System
Classification Name	Motor, Drill, Pneumatic
Device Classification	Class II General, Restorative and Neurological Devices 21 CFR § 882.4370
Predicate Devices	Anspach MRI Surgical Drill System

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Performance Standards

There are no known performance standards established specifically for an iMRI Surgical Drill System or their accessory devices at this time. However, the following standards are applicable to materials; components and/or processes applied to the design, manufacture and distribution of the current (predicate) Anspach iMRI Surgical Drill System, and are applied to the proposed new device.

a) ASTM and other similar recognized material composition-related standards.
b) ASTM F2213-04 "Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in Magnetic Resonance Environment."

c) ASTM F2052-02 "Standard Test Method for Measurement of magnetically induced Displacement Force on Medical Devices in Magnetic Resonance Environment."
d) ISO13485 (2003) Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes 2003-07-15, (In addition to and supplementing US QSR):
e) AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing 1997 (Used with FDA G95-1 Guidelines)
f) AAMI/ANSI/ISO 11137:1994 Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization and ANSI/AAMI/ISO 11137: 1994 (Amended 1:2002) and/or.
g) AMMI TIR 27:2001 Sterilization of Health Care Products – Radiation Sterilization – Substantiation of 25kGY as a Sterilization Dose – Method VDmax*
h) ANSI/AAMI ST37 – Flash Sterilization (Steam)
i) ANSI/AAMI/ISO 11134:1993 Validation of Steam Sterilization
j) CEN EN 1441:1997, Medical Devices – Risk Management*
k) AAMI/ISO 14971-1 Medical Devices – Risk Management – Part 1: Application of risk analysis*
l) GHTF/SG3/N15Rb Final Document – Implementation of risk management Principles and Activities Within a Quality System*

*NOTE: Full conformance to these standards is not intended to be implied or declared, as implementation of various specific aspects of the standards are not yet fully established. These standards are referenced, as current quality system elements affected by requirements of the standards, are under revision to include or exclude (i.e. CEN EN 1441) requirements of the standards as applicable.

This list may not represent all standards routinely used or applied of current or proposed devices.

Device Description

The iMRI Surgical Drill System is a Class II medical device which includes a pneumatic drill motor and foot control; a variety of nosepiece attachments; and various bone dissection tools (cutters). To make the drill system "MRI useable", ferrous metals comprising each system component have been replaced with materials known to have significantly lower or no discernable magnetic susceptibility.

The iMRI Drill System foot control was tested with the Drill System within Zone IV. It was located on the floor within easy access to be activated by the surgeon's foot. The iMRI motor does not require continuous oiling and therefore runs at slower speeds (60 – 65k RPM) than non-iMRI Anspach motors (80 – 85k RPM). Nosepiece attachments (bearing tubes) support the cutter to minimize vibration , wobble and whipping. They are a direct contact (with patient) device and are distributed clean, non-sterile for reusable applications. iMRI cutters are identical to other Anspach non-iMRI cutters with exception of materials and indications for use. Cutters are surgically invasive, direct contact (with patient) devices and are distributed pre-sterilized to a SAL 10^{-6}. iMRI cutters carry additional warnings to advise the user "dulling" may occur faster than other Anspach non-iMRI cutters, especially if overused or reused. Anspach cutters are not designed for and should never be reprocessed for reuse.

Indications for Use

The Anspach iMRI Surgical Drill System (including pneumatic drill motor, foot control, nosepiece attachments and cutters), is indicated for intra-operative (non-imaging) use within a Magnetic Resonance Imaging (MRI) environment rated at 1.5 Tesla or less, for surgical cutting, shaping and removal of bone, including bones of the skull and spine.

Technological Characteristics

The iMRI Drill System (including motor, foot control, nosepiece attachments and cutters), is indicated for intra-operative (non-imaging) use within an MRI system rated at 1.5 Tesla or less, for surgical cutting, shaping and removal of bone, including bones of the skull and spine. The iMRI Surgical Drill System (including drill motor and foot control, nosepiece attachments and cutters), is contraindicated for presence within Zone IV of an iMRI system while imaging is actually being accomplished. Presence of the equipment in Zone IV** during imaging

could cause unacceptable image distortion. Cleaning, sterilization and storage conditions are specified on product package inserts and product labeling complies with US, European Union and in other global market requirements.

Conclusion

The iMRI Drill System is substantially equivalent in form and design to other Anspach pneumatic drill systems including MicroMax, the original 65K, and their nosepiece attachments and cutters. Principle design differences are in materials, indications for use and a slightly modified locking mechanism, which prevents interchangeability between iMRI and non-iMRI system components.

** Zones are based on the definitions listed by the American College of Radiology White Paper on MR Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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The Anspach Effort
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Palm Beach Gardens, Florida 33410

JAN 26 2007

Re: K061297
Trade/Device Name: iMRI Surgical System
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic cranial drill motor
Regulatory Class: II
Product Code: HBB
Dated: January 11, 2007
Received: January 12, 2007

Dear Mr. Banic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061297

Device Name: iMRI Surgical System

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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